

JS 44 (Rev. 11/04)

**CIVIL COVER SHEET**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**

LINDA METCALF, and ROSS METCALF,

**DEFENDANTS**

Merck &amp; Co., Inc.

(b) County of Residence of First Listed Plaintiff Franklin County, Ohio  
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Hunterdon Co., NJ  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Anapol, Schwartz, Weiss, Cohan, Feldman, & Smalley, P.C., 1040 Kings Hwy N., Suite 304. Cherry Hill, NJ 08034, (866) 735-2792

Attorneys (If Known)

Hughes Hubbard & Reed, LLP, 101 Hudson St., Jersey City, NJ 07302, (201) 536-9220

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                                   | DEF                        |   | PTF                        | DEF                                   |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1            | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State                | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5            |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <b>Habeas Corpus:</b> <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition			

**V. ORIGIN**

(Place an "X" in One Box Only)

- ☐ 1 Original Proceeding ☒ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 USC Sec. 1332, 1441 and 1446

Brief description of cause:  
Products Liability action involving prescription medicine Fosamax.

**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

**DEMAND \$**

CHECK YES only if demanded in complaint:

**JURY DEMAND:** ☒ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

Wilfred P. Coronato (WC-6200)  
Bart A. Whitley (BW-3010)  
HUGHES HUBBARD & REED LLP  
A NEW YORK LIMITED LIABILITY PARTNERSHIP  
101 HUDSON STREET, SUITE 3601  
JERSEY CITY, NEW JERSEY 07302-3910  
Telephone: (201) 536-9220  
Attorneys for Defendant Merck & Co., Inc.

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF NEW JERSEY

LINDA METCALF, and	)	
ROSS METCALF, W/H,	)	
	)	
Plaintiffs,	)	Civil Action No. _____
	)	
v.	)	
	)	<b><u>NOTICE OF REMOVAL</u></b>
MERCK & CO., INC.,	)	
	)	
Defendant.	)	

PLEASE TAKE NOTICE that pursuant to 28 U.S.C. §§ 1441 and 1446 Defendant Merck & Co., Inc. ("Merck") hereby gives notice that the above-captioned action, Civil Action No. L-5836-07, pending in the Superior Court of New Jersey, Law Division, Middlesex County, is hereby removed to the United States District Court for the District of New Jersey. In support of removal, Merck respectfully states to the Court the following:

**THE FOSAMAX® MULTIDISTRICT LITIGATION**

1. This action involves allegations regarding the prescription medication FOSAMAX®. On August 16, 2006, the Judicial Panel on Multidistrict Litigation ("MDL Panel") issued an order transferring 18 FOSAMAX® products liability cases to the United States District Court for the Southern District of New York (Keenan, J.) for

coordinated pretrial proceedings under 28 U.S.C. § 1407. *In re Fosamax Products Liability Litigation*, MDL No. 1789. Processes for quickly sending additional related cases to Judge Keenan have been set in place. To date, the MDL Panel has issued 26 Conditional Transfer Orders, at least 67 cases involving FOSAMAX® have been transferred to MDL-1789, and there are a total of 169 cases pending in the MDL, including cases filed directly in the Southern District of New York.. Merck will seek the transfer of this action to MDL-1789, and will in the next week provide the MDL Panel notice of this action pursuant to the “tag-along” procedure contained in the MDL Rules.

### **GROUND FOR REMOVAL**

2. On or about June 29, 2007, Plaintiffs commenced this action entitled *Metcalf, et al., v. Merck & Co., Inc.*, Case No. L-5836-07, against Merck in the Superior Court of New Jersey, Law Division, Middlesex County.

3. For the reasons set forth in more detail below, this Court should assume jurisdiction over this action pursuant to 28 U.S.C. § 1332 because this matter is a civil action in which the amount in controversy exceeds the sum of \$75,000, exclusive of costs and interest, and is between citizens of different states.

#### **I. MERCK HAS SATISFIED THE PROCEDURAL REQUIREMENTS FOR REMOVAL.**

4. Plaintiffs filed their Complaint in the Superior Court of New Jersey, Law Division, Middlesex County on or about June 29, 2007. Merck has not yet been served with a copy of the Complaint. This Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b).

5. No further proceedings have been had in this action.

6. Venue is proper in this Court because it is “the district and division embracing the place where such action is pending.” *See* 28 U.S.C. § 1441(a). Therefore, this action is properly removed to the District of New Jersey pursuant to 28 U.S.C. § 110.

7. No previous application has been made for the relief requested herein.

8. Pursuant to 28 U.S.C. § 1446(a), copies of all process, pleadings, and orders received by Merck, which include the Complaint and Civil Cover Sheet, are attached hereto at Exhibits A and B.

9. Pursuant to 28 U.S.C. § 1446(d), a copy of this Notice of Removal is being served upon counsel for Plaintiff and a copy is being filed with the Clerk of the Superior Court of New Jersey, Law Division, Middlesex County.

**II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332 AND 1441.**

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because this is a civil action in which the amount in controversy exceeds the sum of \$75,000, exclusive of costs and interest, and is between citizens of different states.

**A. The amount in controversy requirement is satisfied.**

11. It is apparent from the face of the Complaint that Plaintiff Linda Metcalf seeks recovery of an amount in excess of \$75,000, exclusive of costs and interest. Mrs. Metcalf alleges that, as a result of ingesting FOSAMAX®, she developed “osteonecrosis of the jaw,” which Plaintiff alleges “is a serious medical event and can result in severe disability and death,” causing her to suffer “diffuse jaw pain and the loss of bone mass

in the jaw.” (Complaint ¶ 3, 15, 28). Mrs. Metcalf claims that, as a result of using FOSAMAX®, she suffered “severe mental and physical pain and suffering, “ as well as “permanent injuries and emotional distress.” (Complaint ¶ 29.) Plaintiff Ross Metcalf alleges that he is entitled to damages for loss of consortium. (Complaint, Count VII). The Plaintiffs seek both compensatory and “treble and punitive damages.” (Complaint at 7, 15).

12. While there is not a record of prior cases that specifically involve osteonecrosis of the jaw – a fact which may be attributable to the fact that osteonecrosis of the jaw is a rare disorder and cases alleging liability against pharmaceutical manufacturers for allegedly causing the same had, prior to very recently, been non-existent – there are:

- numerous reported cases in which jaw or similar facial injury led to jury or court awards far in excess of \$75,000. *See, e.g., Howie v. Walsh*, 609 S.E.2d 249 (N.C. App. 2005) (addressing jury award of \$300,000 against dentist who fractured patient’s jaw during procedure); *Becker v. Woods*, 806 N.Y.S.2d 704 (N.Y. App. Div. 2005) (affirming jury award of \$840,000 in damages where dental patient suffered from permanent paresthesia); *Preston v. Dupont*, 35 P.3d 433 (Colo. 2001) (addressing jury award of more than \$250,000 for damage to alveolar nerve in jaw); *Bowers v. Liuzza*, 769 So.2d 88 (La. App.), *writ. denied*, 776 So.2d 468 (La. 2000) (finding that minimum adequate damage award for nerve damage in jaw was an amount that exceeded \$175,000); *Becker v. Halliday*, 554 N.W. 2d 67 (Mich. App. 1996) (jury award of \$200,000 in

damages, where syringe lodged in upper jaw); *Herpin v. Witherspoon*, 664 So.2d 515 (La. App. 1995) (plaintiff entitled to receive more than \$75,000 as a result of temporomandibular joint (TMJ) dysfunction); *Washburn v. Holbrook*, 806 P.2d 702 (Or. App. 1991) (affirming jury finding of \$400,000 in damages as a result of damage to jaw during root canal); and

- numerous prior cases that reveal that potential awards based on osteonecrosis or avascular necrosis of the hip, knee, or other joint, exceed the \$75,000 jurisdictional amount. *See, e.g., Barbee v. United States*, 2005 W.L. 3336504, at \*1-2 (W.D. Wis. 2006) (finding that plaintiff suffered nearly \$700,000 in damages for hip injuries that included avascular necrosis); *Shaver v. United States*, 319 F.Supp. 2d 649 (M.D.N.C. 2004) (awarding more than \$75,000 in damages for osteonecrosis in knee caused by automobile accident); *Piselli v. 75<sup>th</sup> Street Medical*, 808 A.2d 508 (Md. 2002) (addressing jury award of \$410,000 for medical malpractice that led to avascular necrosis of the hip); *Collier v. Cawthon*, 570 S.E.2d 53 (Ga. App. 2002) (affirming jury award of \$170,000 for avascular necrosis of the hip).

13. The Plaintiff's claims of "severe and permanent" injuries, and the compensatory and punitive damages that they seek thus far exceed this Court's minimum \$75,000 jurisdictional limit.

**B. There is complete diversity between the parties.**

14. According to the Complaint, Plaintiffs were at the time of the filing of the Complaint and are now citizens of Ohio. (Complaint ¶¶ 1-2.)

15. Merck is now, and was at the time Plaintiff commenced this action, a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey and, therefore, is a citizen of New Jersey for purposes of determining diversity. 28 U.S.C. § 1332(c)(1). (Complaint ¶ 4.)

16. Hence, there is complete diversity between the parties, and this court has subject matter jurisdiction under 28 U.S.C. § 1332.

**C. The action is properly removed under 28 U.S.C. § 1446 because no defendant that has been *joined and served* is a resident of New Jersey.**

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17. Merck removes this case pursuant to § 1441(b) on the grounds that “none of the parties in interest *properly joined and served* as defendants is a citizen of the state in which such action is brought.” 28 U.S.C. § 1441(b) (emphasis added).

18. At the time of the filing of this Notice of Removal, Merck has not been served with a summons and complaint in this action.

19. As this Court held in *Frick v. Novartis Pharmaceuticals Corp.*, 2006 W.L. 454360 (D.N.J. 2006), removal of this case is proper under the plain language of 28 U.S.C. § 1441(b), because there is no defendant in this case who has been properly joined and served and who is a resident of New Jersey, the state in which this action was brought. *Frick*, 2006 W.L. 454360, at \*3.



WHEREFORE, Defendant Merck respectfully removes this action from the Superior Court of New Jersey, Law Division, Middlesex County to this Court pursuant to 28 U.S.C. § 1441.

Dated: July 3, 2007

HUGHES HUBBARD & REED LLP  
A New York Limited Liability Partnership  
Attorneys for Defendant  
Merck & Co., Inc.

By: s/ Bart A. Whitley  
Wilfred P. Coronato  
Bart A. Whitley

**CERTIFICATION OF SERVICE**

I hereby certify that a copy of the within Notice of Removal as well as a Notice of Filing Notice of Removal was served this day by facsimile and Federal Express in compliance with Rule 5 of the Federal Rules of Civil Procedure upon counsel for plaintiff, Tracy A. Finken, Esq., Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, P.C., 1040 Kings Highway North, Cherry Hill, New Jersey 08034.

Dated: July 3, 2007

By: /s Bart A. Whitley  
Wilfred P. Coronato  
Bart A. Whitley



# EXHIBIT A

ANAPOL, SCHWARTZ, WEISS, COHAN  
FELDMAN & SMALLEY, P.C.

BY: DAVID JACOBY, ESQUIRE  
TRACY A. FINKEN, ESQUIRE  
GREGORY S. SPIZER, ESQUIRE

1040 KINGS HIGHWAY NORTH  
CHERRY HILL, NJ 08034  
(856) 482-1600; FAX (856) 482-1911  
ATTORNEY FOR PLAINTIFFS

2007 JUN 29 PM 11:10

FILED & RECEIVED

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IN THE SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION – MIDDLESEX COUNTY

LINDA METCALF, and  
ROSS METCALF, W/H  
Plaintiffs

v.

MERCK & CO., INC.  
Defendant

Civil Action No. L-5836-07

Fosamax Litigation

COMPLAINT, DEMAND  
FOR JURY TRIAL,  
DESIGNATION OF TRIAL  
COUNSEL AND NOTICE OF  
NO OTHER ACTIONS

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Plaintiffs, Linda and Ross Metcalf, by way of Complaint against Defendant, upon  
information and belief, alleges as follows:

**PARTIES—PLAINTIFFS**

1. Plaintiff, Linda Metcalf, is a citizen of Ohio, residing at 5419 Lanark Court,  
Dublin, Ohio 43017-8540.

2. Plaintiff, Ross Metcalf, is a citizen of Ohio, residing at 5419 Lanark Court,  
Dublin, Ohio 43017-8540.

3. Plaintiff, Linda Metcalf, regularly ingested Fosamax in the months and years  
leading up to her diagnosis of osteonecrosis of the jaw.

## PARTIES—DEFENDANT

4. Defendant, Merck & Co., Inc. (hereinafter “Merck”), is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at One Merck Drive, White House Station, NJ 08889.

5. At all times relevant hereto, Defendant Merck was engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third parties or related entities, the pharmaceutical, Fosamax.

6. At all relevant times, Defendant was responsible for, or involved in, designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing and/or selling its product, the prescription drug Fosamax.

7. In September 1995, the United States Food and Drug Administration (“FDA”) approved Defendant’s compound alendronate for various uses, including the treatment of osteoporosis and Paget’s Disease. Alendronate is marketed by Defendant as “Fosamax.”

8. Fosamax falls within a class of drugs known as bisphosphonates, which are used for treating bone conditions such as osteopenia, osteoporosis and Paget’s disease. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etrinodate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference (“PDR”) for Fosamax confirms that the molecule contains a nitrogen atom.

9. Throughout the 1990’s and 2000’s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the

nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Defendant, particularly with its heightened knowledge and experience, knew or should have known that Fosamax, as a nitrogenous bisphosphonates, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

10. Defendant, particularly with its heightened knowledge and experience, knew or should have known that bisphosphonates, including Fosamax, inhibit endothelial cell function. Similarly, Defendant, particularly with its heightened knowledge and experience, knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patient's mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

11. Defendant, particularly with its heightened knowledge and experience, also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That, in turn, can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

12. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on Fosamax.

13. Once the jaw complications begin and become symptomatic, they are very difficult to treat and typically are not reversible.

14. Shortly after Defendant began selling Fosamax, reports of osteonecrosis of the jaw and other various dental complications among Fosamax users began surfacing, indicating

that Fosamax shared the effects of other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to osteonecrosis of the jaw, Defendant proposed further uses of Fosamax, such as Fosamax-D, and sought to extend the exclusivity period of Fosamax through 2018.

15. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

16. Since Fosamax was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of Fosamax.

17. On August 24, 2004, the FDA posted its ODS Postmarketing Safety Review on bisphosphonates, including Fosamax. This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

18. As a result of the FDA review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, Fosamax.

19. Thereafter, the FDA recommended and stated that the labeling for Fosamax should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw. Defendant refused to accede to the FDA's request.

20. Rather than warn patients, and despite Defendant's knowledge about the increased risk of osteonecrosis of the jaw on patients using Fosamax, Defendant continued to defend Fosamax, mislead physicians and the public, and minimize unfavorable findings.

21. Fosamax is one of Defendant's top selling drugs, averaging more that \$3 billion a year in sales.

22. Consumers, including Plaintiff, who have used Fosamax for treatment of osteoporosis, had several alternative safer products available to treat their condition.

23. Defendant knew of the significant risk of dental and oral complications caused by ingestion of Fosamax, but Defendant did not adequately and sufficiently warn consumers, including Plaintiffs, or the medical community, of such risks.

24. As a direct result, Plaintiff was prescribed Fosamax and has been permanently injured, having suffered serious injuries and damages from the ingestion of Fosamax. Plaintiff requires and will in the future require ongoing medical care and treatment.

25. Plaintiffs have suffered mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained form the use of Fosamax.

26. Plaintiff was prescribed and began taking Fosamax on or about June of 2000.

27. Plaintiff used Fosamax as prescribed and in a foreseeable manner.

28. As a direct and proximate result of using Fosamax, Plaintiff has suffered diffuse jaw pain and the loss of bone mass in the jaw and is currently in treatment for her condition.

29. Plaintiff, as a direct and proximate result of using Fosamax, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

30. Plaintiff used Fosamax which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

31. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known of the risks of Fosamax and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

32. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking Fosamax.

33. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

**COUNT I**  
**PLAINTIFFS v. MERCK**  
**PRODUCTS LIABILITY—FAILURE TO WARN (N.J.S.A. 2A:58C-2 et seq.)**

34. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

35. Defendant Merck researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, Fosamax, and in the course of same, directly advertised or marketed the product to the FDA, consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Fosamax.

36. Fosamax was under the exclusive control of Defendant as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of Fosamax, and the comparative severity, duration and the extent of the risk of injury with such use.



37. Defendant Merck has failed to timely and reasonably warn of material facts regarding the safety and efficacy of Fosamax so that no medical care provider would have prescribed, or no consumer would have used Fosamax had those facts been made known to such providers and consumers.

38. Defendant Merck has failed to perform or otherwise facilitate adequate testing in that such testing would have shown that Fosamax posed serious and potentially life-threatening side effects and complications with respect to which full and proper warnings accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA and the public, including Plaintiffs.

39. Fosamax, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendant, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendant knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of Fosamax, Defendant failed to provide adequate warnings to medical care providers, the FDA and the consuming public, including Plaintiffs, and continued to promote Fosamax aggressively.

40. As direct and proximate result of the conduct of Defendant Merck as aforesaid, Plaintiff was diagnosed with osteonecrosis of the jaw causing permanent injury to Plaintiff, Linda Metcalf, and causing physical, emotional and economic injury to Plaintiffs.

**WHEREFORE**, Plaintiffs demand judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT II**  
**PLAINTIFFS v. MERCK**  
**PRODUCTS LIABILITY—DEFECTIVE DESIGN (N.J.S.A. 2A:58C-2 et seq.)**

41. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

42. Defendant is a researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of Fosamax, which is defective and unreasonably dangerous to consumers.

43. The aforementioned drug is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The aforementioned drug is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than similar drugs on the market and is more dangerous than ordinary consumers can reasonably foresee.

44. The defective condition of the aforementioned drug renders it unreasonably dangerous, and it was in this defective condition at the time it left the hands of Defendant. The aforementioned drug was expected to and did reach consumers, including Plaintiffs, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

45. Plaintiffs were unaware of the significant hazards and defects in the aforementioned drug. The aforementioned drug was unreasonably dangerous in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff was taking the aforementioned drug, the medication was being utilized in a manner that was intended by Defendant. At the time Plaintiff received and consumed the aforementioned drug, it was represented to be safe and free from latent defects.

46. Defendant is strictly liable to Plaintiffs for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendant because of the design defects.

47. Defendant knew or should have known of the danger associated with the use of the aforementioned drug, as well as the defective nature, but has continued to design, manufacture, sell, distribute, market, promote and/or supply the aforementioned drug so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the aforementioned drug.

48. As a direct and proximate cause of the design defect and Defendant's misconduct as set forth herein, Plaintiff was diagnosed with osteonecrosis of the jaw causing permanent injury and causing physical, emotional and economic injury to Plaintiffs.

**WHEREFORE**, Plaintiffs demand judgment against Defendant for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT III**  
**PLAINTIFFS v. MERCK**  
**PUNITIVE DAMAGES UNDER THE PRODUCTS LIABILITY ACT (N.J.S.A.2A:58C-1)**

49. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

50. Plaintiffs are entitled to punitive damages because Defendant's failure to warn was reckless and without regard for the public's safety and welfare. Defendant misled both the medical community and the public at large, including Plaintiffs herein, by making false representations about the safety of Fosamax. Defendant downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the

use of Fosamax despite available information demonstrating that Fosamax was likely to cause serious and even fatal side effects to users.

51. Defendant was or should have been in possession of evidence demonstrating that Fosamax caused serious side effects. Nevertheless, Defendant continued to market Fosamax by providing false and misleading information with regard to safety and efficacy.

52. Defendant failed to provide warnings that would have dissuaded physicians from prescribing Fosamax and consumers from purchasing and consuming Fosamax, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Fosamax.

**WHEREFORE**, Plaintiffs demand judgment against Defendant Merck for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

**COUNT IV  
PLAINTIFFS v. MERCK  
BREACH OF EXPRESS WARRANTY**

53. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

54. Merck manufactured, sold, distributed, marketed, and/or promoted Fosamax used by Plaintiff, and this drug was expected to, and did reach Plaintiff without a substantial change in condition.

55. Defendant Merck, its agents and employees, in manufacturing, selling, distributing, supplying, marketing and/or promoting the drug Fosamax, expressly warranted that the drug was safe and effective as a medication for osteoporosis.

56. Defendant Merck, its agents and employees, breached this warranty in that Fosamax was not safe and effective for its intended, reasonably foreseeable use as a medication for osteoporosis because of the risk of osteonecrosis of the jaw associated with its use and in light of other risks of serious injuries to foreseeable users.

57. Defendant Merck, its agents and employees, failed to provide adequate warnings with Fosamax, rendering it unreasonably dangerous and unfit for the intended, reasonably foreseeable purposes for which it is used, in breach of warranty.

58. Plaintiff justifiably and detrimentally relied upon the warranties and representations of Defendant in the purchase and use of the product.

59. As a direct and proximate result of the acts and omissions of Defendant, Plaintiff ingested Fosamax and developed osteonecrosis of the jaw which resulted in physical impairment and other injuries. As a further direct and proximate result of the acts and omissions of Defendant, Plaintiff has been prevented from pursuing normal activities and employment, has experienced severe pain and suffering and mental anguish, and has been deprived of ordinary pursuits and enjoyments of life.

**WHEREFORE**, Plaintiffs demand judgment against Defendant for compensatory damages, punitive damages and costs of suit as provided by law.

**COUNT V**  
**PLAINTIFFS v. MERCK**  
**VIOLATION OF CONSUMER FRAUD ACT**

60. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

61. Fosamax is a "good" as that term is defined in the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*, hereinafter, the ("Act").

62. Defendant, Merck, is a "person", "company", or "seller" as that term is defined the Act, and as such, is prohibited from engaging in deceptive acts and practices, as set forth more fully below.

63. The Act prohibits deceptive acts and practices, including but not limited to passing off goods as those of another; representing that goods have specific sponsorship, approval, characteristics, ingredients, benefits, affiliation or status that they do not have; or engaging in fraudulent or deceptive conduct which creates the likelihood of confusion or misunderstanding.

64. The following acts, uses or employments by Defendant constitute unconscionable commercial practices, deceptions, frauds, false pretenses, false promises, misrepresentations, or the knowing concealment, suppression, or omission of material facts with intent that Plaintiffs rely upon such concealment, suppression or omission, in connection with the sale and marketing of Fosamax, are unlawful under the Act:

- (a) Defendant, having undertaken the manufacturing, marketing, dispensing, distribution, and promotion of the drug described herein, owed a duty to provide accurate and complete information regarding this product;
- (b) Defendant's advertising program, by affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of Fosamax was safe for human use and did not have unacceptable side effects;
- (c) On information and belief, Defendant misrepresented to Plaintiffs and to members of the general public its knowledge about the propensities of the product to cause injuries such as those sustained by Plaintiff. Defendant

concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of Fosamax. Defendant falsely and deceptively kept relevant information from Fosamax users and minimized concerns regarding the safety of Fosamax to induce Plaintiff and the general public to purchase and use Fosamax;

- (d) In justifiable and detrimental reliance on the truth of Defendant's representations about the safety of Fosamax, Plaintiff purchased the product and used the product in the manner and for the purpose intended as represented and instructed by Defendant; and
- (e) the representations, misrepresentations, acts and omissions made by Defendant deprived Plaintiff and other foreseeable users of Fosamax of the opportunity of free choice as to whether or not to expose themselves to the aforementioned dangers of ingesting Fosamax.

65. As a direct and proximate result of Plaintiff's lack of awareness of the dangers of Fosamax, caused by the acts and omissions of Defendant, Plaintiff ingested Fosamax and developed osteonecrosis of the jaw which resulted in physical impairment and other injuries.

66. As a further direct and proximate result of the acts and omissions of Defendant, Plaintiff has been prevented from pursuing her normal activities and employment, has experienced severe pain and suffering and mental anguish, and has been deprived of ordinary pursuits and enjoyments of life.

**WHEREFORE**, Plaintiffs demand judgment against Defendant for compensatory damages, punitive damages and costs of suit as provided by law.



**COUNT VI  
PLAINTIFFS V. MERCK  
NEW JERSEY PRODUCTS LIABILITY ACT**

67. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

68. Defendant is liable to plaintiff pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 *et seq.*

69. Defendant is under a duty to supply a product that is reasonably fit, suitable or safe for its intended use, such that it is not unreasonably dangerous and such that it does not cause injury to a reasonably foreseeable user.

70. Defendant has failed to meet the obligation of supplying a product that is reasonably fit, suitable or safe for its intended purpose and which is not unreasonably dangerous, in that they have placed the product Fosamax into the stream of commerce when Fosamax had been defectively manufactured, defectively designed and failed to contain adequate warnings, labels or instructions.

71. Plaintiffs alleges that at all times, the product Fosamax was defective when it left Defendant's control and the product was not substantially altered prior to reaching Plaintiff.

72. As a direct and proximate result of the acts and omissions of Defendant, Plaintiff, a reasonably foreseeable consumer, ingested Fosamax and developed osteonecrosis of the jaw which resulted in physical impairment and other injuries. As a further direct and proximate result of the acts and omissions of Defendant, Plaintiff has been prevented from pursuing her normal activities and employment, has experienced severe pain and suffering and mental anguish, and has been deprived of her ordinary pursuits and enjoyments of life.

**WHEREFORE**, Plaintiffs demand judgment against Defendant for compensatory damages, punitive damages and costs of suit as provided by law.

**COUNT VII  
PLAINTIFFS v. MERCK  
LOSS OF CONSORTIUM**

73. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

74. Plaintiff, Ross Metcalf, is the husband of Plaintiff, Linda Metcalf.

75. As a result of the injuries suffered by his wife as aforesaid, Plaintiff, Ross Metcalf, has and will in the future suffer the loss of usual services and consortium of his wife and has been required to provide special services and care to her.

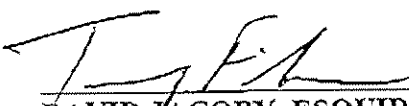
**WHEREFORE**, Plaintiffs demand judgment against Defendant for compensatory damages, punitive damages and costs of suit as provided by law.

**DEMAND FOR TRIAL BY JURY**

Plaintiffs demand a trial by jury as to all Counts.

Respectfully submitted,

**ANAPOL, SCHWARTZ, WEISS, COHAN  
FELDMAN & SMALLEY, P.C.**

  
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**DAVID JACOBY, ESQUIRE  
TRACY A. FINKEN, ESQUIRE  
GREGORY S. SPIZER, ESQUIRE  
Attorneys for Plaintiff**

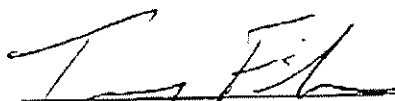
Dated: 6/28/07

**DESIGNATION OF TRIAL COUNSEL**

Pursuant to R. 4:25-4, David Jacoby, Esquire, Tracy A. Finken, Esquire, and Gregory S. Spizer, Esquire, along with Sol H. Weiss, Esquire, pending his admission, are hereby designated as trial counsel for Plaintiffs in the within matter.

Respectfully submitted,

ANAPOL, SCHWARTZ, WEISS, COHAN  
FELDMAN & SMALLEY, P.C.

  
\_\_\_\_\_  
DAVID JACOBY, ESQUIRE  
TRACY A. FINKEN, ESQUIRE  
GREGORY S. SPIZER, ESQUIRE  
Attorneys for Plaintiff

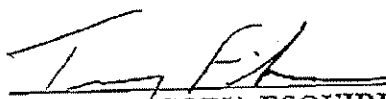
Dated: 6/28/07

**NOTICE OF OTHER ACTION**

Pursuant to R. 4:5-1, I hereby certify that the matter in controversy is not the subject of any other pending or contemplated court action, arbitration or worker's compensation claim.

Respectfully submitted,

ANAPOL, SCHWARTZ, WEISS, COHAN  
FELDMAN & SMALLEY, P.C.

  
\_\_\_\_\_  
DAVID JACOBY, ESQUIRE  
TRACY A. FINKEN, ESQUIRE  
GREGORY S. SPIZER, ESQUIRE  
Attorneys for Plaintiff

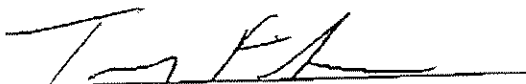
Dated: 6/28/07

**CERTIFICATION**

The undersigned certifies that to the best of my knowledge this matter is not the subject of any other legal or arbitration proceeding in the Courts of New Jersey. The undersigned further certifies that to the best of my knowledge, no other persons should be a party to this matter other than those named in this Complaint.

Respectfully submitted,


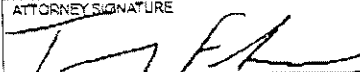
ANAPOL, SCHWARTZ, WEISS, COHAN  
FELDMAN & SMALLEY, P.C.



DAVID JACOBY, ESQUIRE  
TRACY A. FINKEN, ESQUIRE  
GREGORY S. SPIZER, ESQUIRE  
Attorneys for Plaintiff

Dated: 6/28/07

# EXHIBIT B

CIVIL CASE INFORMATION STATEMENT (CIS)		FOR USE BY CLERK'S OFFICE ONLY	
 <p>Use for initial Law Division - Civil Part pleadings (not motions) under Rule 4:5-1. Pleading will be rejected for filing, under Rule 1:5-6(c), if information above the black bar is not completed or if attorney's signature is not affixed.</p>		PAYMENT TYPE: CK CG CA	
		CHG / CK NO.	
		AMOUNT:	
		OVERPAYMENT:	
		BATCH NUMBER:	
ATTORNEY/PROSE NAME David Jacoby, Esq. & Tracy A. Finken, Esq.	TELEPHONE NUMBER (856) 482-1600	COUNTY OF VENUE Middlesex County	
FIRM NAME (if applicable) Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, P.C.		DOCKET NUMBER (when available) L-5836-07	
OFFICE ADDRESS 1040 Kings Highway North, Suite 304 Cherry Hill, NJ 08034		DOCUMENT TYPE Complaint	
		JURY DEMAND <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
NAME OF PARTY (e.g. John Doe, Plaintiff) Linda Metcalf & Ross Metcalf, W/H	CAPTION Metcalf v. Merck & Co., Inc.		
CASE TYPE NUMBER (See reverse side for listing) 606	IS THIS A PROFESSIONAL MALPRACTICE CASE? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YOU HAVE CHECKED "YES," SEE N.J.S.A. 2A:55A-27 AND APPLICABLE CASE LAW REGARDING YOUR OBLIGATION TO FILE AN AFFIDAVIT OF MERIT.		
RELATED CASES PENDING? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	IF YES, LIST DOCKET NUMBERS		
DO YOU ANTICIPATE ADDING ANY PARTIES (arising out of same transaction or occurrence)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	NAME OF DEFENDANT'S PRIMARY INSURANCE COMPANY, IF KNOWN <input type="checkbox"/> NONE <input checked="" type="checkbox"/> UNKNOWN		
<b>THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE.</b>			
CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION			
A. DO PARTIES HAVE A CURRENT, PAST OR RECURRENT RELATIONSHIP? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		IF YES, IS THAT RELATIONSHIP <input type="checkbox"/> EMPLOYER-EMPLOYEE <input type="checkbox"/> FRIEND/NEIGHBOR <input type="checkbox"/> OTHER (explain) _____ <input type="checkbox"/> FAMILIAL <input type="checkbox"/> BUSINESS	
B. DOES THE STATUTE GOVERNING THIS CASE PROVIDE FOR PAYMENT OF FEES BY THE LOSING PARTY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
USE THIS SPACE TO ALERT THE COURT TO ANY SPECIAL CASE CHARACTERISTICS THAT MAY WARRANT INDIVIDUAL MANAGEMENT OR ACCELERATED DISPOSITION:			
DO YOU OR YOUR CLIENT NEED ANY DISABILITY ACCOMMODATIONS? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		IF YES, PLEASE IDENTIFY THE REQUESTED ACCOMMODATION: _____	
WILL AN INTERPRETER BE NEEDED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		IF YES, FOR WHAT LANGUAGE: _____	
ATTORNEY SIGNATURE 			

Revised July 2001